

**OFFICE OF THE CENTER DIRECTOR**

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**Management of the Regulatory Science and Review Enhancement Committee**

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**PURPOSE**

This MAPP describes:

- The role and responsibilities of the Center for Drug Evaluation and Research (CDER) Regulatory Science and Review Enhancement (RSR) Committee
  - The structure and function of the RSR Committee
  - The responsibilities of those designated to serve on the RSR Committee
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**BACKGROUND**

As part of the Agency's mission to ensure that safe and effective drugs are available to the American people, CDER seeks to enable, support, and effectively use regulatory science and review enhancement projects initiated by Center scientists.

The primary purpose for such projects is to assist Agency management and staff in

1. Improving information management, making better use of the information available to the Agency
2. Meeting the regulatory objectives of CDER
3. Disseminating to regulated industry relevant scientific information on planning and designing drug trials and analyzing data from these trials

The secondary purpose of these projects is to support CDER staff through professional development activities.

## ORGANIZATION

1. **Co-Chairs** — The Co-chairs of the RSR Committee are designated by the Deputy Center Director.
  2. **Project Manager** — The Project Manager represents the Office of Executive Programs (OEP), and is designated by the Director of OEP and approved by the Deputy Center Director.
  3. **Members** — In addition to the Co-chairs, members of the RSR Committee include representatives of all scientific disciplines in CDER. Members are designated by the RSR Co-chairs and approved by the Center Director.
  4. **Other Participants** — Other participants on the RSR Committee represent CDER's Office of Information Technology (OIT). These participants are designated by the Director of OIT and approved by the RSR Co-chairs and the Deputy Center Director. These participants are not voting members of the committee.
  5. **The Deputy Center Director** — The Deputy Center Director will provide oversight for the RSR.
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## RESPONSIBILITIES

- **The RSR Committee will:**

1. Ensure that the evaluation of research proposals is carried out with consideration of CDER's mission, vision, and values, and the relationship of CDER programs to the programs in other FDA Centers and Government agencies.
2. Assist in the identification of CDER regulatory science research needs and priorities.
3. Ensure that the RSR Committee efforts are focused on the scientific areas that will provide the greatest benefits to the Agency's mission and the public health.
4. Provide advice to the Deputy Center Director on regulatory scientific research projects to be funded.

- **The Co-chairs of the RSR will:**

1. Ensure that the responsibilities of the RSR Committee are carried out in accordance with this MAPP and other Agency and Center policies and procedures.
  2. Ensure that recommendations developed by the RSR Committee are communicated to the Deputy Center Director.
  3. Ensure that RSR Committee meetings are held as needed and that issues discussed are prioritized.
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4. Ensure that all CDER constituencies have input into the RSR process and that all CDER regulatory science research projects are reviewed by the RSR Committee.
  5. Co-chair meetings of the RSR Committee.
  - **The Project Manager will:**
    1. Schedule and coordinate meetings. Issues to be brought before the RSR Committee should be directed to the attention of the Project Manager, who will discuss the issues with the Co-chairs of the committee before making up the agenda.
    2. Act as liaison between the principal investigators and the RSR Committee throughout the entire funding cycle, keeping them informed on the status of the approval for funding.
    3. Distribute documents.
    4. Maintain files of RSR Committee activities.
    5. Prepare minutes of the meetings. Meeting minutes will be sent to every committee member and filed on the shared drive that is available to committee members and participants.
    6. Ensure the accuracy of RSR documents.
    7. Oversee the budget and distribution of funds to support RSR projects.
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## PROCEDURES

- **Process of the review cycle:**
    1. Priorities for funding under the RSR Program will be established by CDER management, the scientific coordinating committees, and the RSR Committee.
    2. The Project Manager will issue an announcement of available funding, requesting that interested candidates in CDER submit concept papers describing potential projects.
    3. At least one RSR Committee member will review each concept paper. The committee Co-chairs will assign papers to committee members based on scientific expertise on the subject matter.
    4. The RSR Committee will meet to rate and rank the concept papers.
      - (a) The RSR member who reviews the concept paper will present it to the committee with a recommendation on funding.
      - (b) Each concept paper will be rated on a scale of 2.5 to 15 based on the reviewer's recommendation.
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- (c) Only those papers rating at least 7.5 will be asked to submit full proposals. Based on budget considerations and the number of papers submitted, the rating cutoff may be higher than 7.5.
  - (d) To vote on the paper, committee members must be present at the meeting, and must have been present during the presentation of the paper.
  - (e) Committee members who are supervisors of a principal investigator are excused from participation in the meeting during the discussion and voting on that individual's paper.
- 5. Full proposals (applications) will be submitted to the RSR Committee, accompanied by a signed letter of intent. The applicant and his or her supervisor, division director, and office director will sign the proposal and letter of intent.
- 6. At least one RSR Committee member, at least one non-member from the appropriate discipline, and (where applicable) at least one scientific coordinating committee member will review each proposal.
- 7. The RSR Committee will meet to rate and rank the full proposals.
  - (a) The RSR Committee members who review the proposal will present it to the committee with a recommendation on funding.
  - (b) Each proposal will be rated on a scale from 2.5 to 15 based on the reviewer's recommendation.
  - (c) Only those proposals rating at 7.5 and above will be considered for funding. The total amount of available funding will determine the number of proposals that will be funded. The proposals with the highest ratings will be selected.
  - (d) To vote on the proposal, members must be present at the meeting, and must have been present during the presentation of the proposal.
  - (e) Committee members who are supervisors of a principal investigator are excused from participating in the meeting during the discussion and voting on that individual's proposal.
- Meetings of the RSR Committee will be scheduled as needed. Need will be determined by the cycle of funding for new RSR projects. There will generally be three meetings a year.
  - 1. The first meeting is to rate the Center's priorities for funding. This meeting may take place through e-mail or a teleconference.
  - 2. The second meeting is to rate and rank concept papers.
  - 3. The third meeting is to rate and rank the full proposals.

Other meetings may be called as needed, but are not held on a routine basis.

- Voting — Projects to be funded are selected by a rating and ranking process where each member provides a rating to each proposal. The Project Manager tallies the votes. Individual votes remain confidential.
  - Quorum — At least a simple majority of the members of the RSR Committee must be present to rate and rank projects.
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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.